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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/765,695	07/25/1997	LARS ABRAHMSEN	A96335US	6468

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FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	45

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/765,695	Applicant(s) Abrahmsen et al.
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *36 and 53-57* is/are pending in the application.

4a) Of the above, claim(s) *53-57* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *36* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. In view of the Brief filed on 9/18/2002, PROSECUTION IS HEREBY REOPENED.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(a) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(b) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. Claim 36 is under consideration.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed polypeptide.

Claim 36 recites use of a conjugate containing a mutated peptide wherein the peptide has been mutated to show a modified ability to bind MHC class II, binds VB of a T cell receptor and can be used to treat disease in a mammal. The specification discloses a single example of a mutant that has all these properties (see page 21, last two sentences

continued on next page). However, the claims encompass use of a vast undescribed genus of mutants with the aforementioned functional properties. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification discloses a single example of a mutant that has all the required functional properties of the peptide used in the claims whilst the claims encompass use of a vast undescribed genus of mutants with the aforementioned functional properties.

The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence

of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 36 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Dohlsten et al. (1991).

Dohlsten et al. teach SEA/ antibody conjugates wherein the SEA portion of the conjugate portion binds T cells and the antibody portion of the conjugate binds a tumor antigen (see Abstract). Dohlsten et al. teach that said conjugate can activate T cells to lyse tumor cells that express the antigen bound by the antibody portion of the SEA/antibody conjugate (see abstract). Dohlsten et al. teach that SEA binds VB of the TCR of T cells. Dohlsten et al. teach that said conjugates can be used to treat disease (see Abstract, last sentence) including cancer (see page 9291, second column). SEA is a superantigen requiring zinc ions for binding to MHC class II (eg. see claim 50). The SEA and antibody are "fused together". SEA is as staphylococcal enterotoxin (see Abstract). An antibody is a "polypeptide structure" and a "biospecific affinity counterpart" (see claim 45). Dohlsten et al. do not teach that the superantigen portion of the conjugate has been mutated to show a modified ability to bind to MHC class II. Regarding the SEA/antibody disclosed in said publication, Dohlsten et al. teach that "it would be of importance to further perturb MHC class II-dependent CTL activity by reducing the binding of the C215-SEA conjugate for MHC class II molecules" (see page 9291, column 1). Dohlsten et al. teach that MHC class II binding in SEA and other superantigens has been localized to the C-terminal region (see page 9291, first column). Dohlsten et al. teach that using such information, SEA/antibody conjugates with reduced MHC class II binding could be prepared (see column 1, page 9291). A routineer would have prepared such conjugates using routine experimentation. Dohlsten et al. teach that it would have been desirable to produce such mutated conjugates to decrease binding of the conjugate to nontumor cells which express

MHC class II (see column 1, page 9291). The zinc binding region of the superantigen is found in the C-terminus. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Dohlsten et al. teach SEA/ antibody conjugates wherein the SEA portion of the conjugate portion binds T cells and the antibody portion of the conjugate binds a tumor antigen and the use of said conjugates to kill tumor cells, and Dohlsten et al. teach that "it would be of importance to further perturb MHC class II-dependent CTL activity by reducing the binding of the C215-SEA conjugate for MHC class II molecules". One of ordinary skill in the art would have been motivated to prepare such conjugates because Dohlsten et al. teach that "it would be of importance to further perturb MHC class II-dependent CTL activity by reducing the binding of the C215-SEA conjugate for MHC class II molecules".

Regarding applicants comments about Kim et al., Kim et al. is drawn to TSST-1. TSST-1 is not one of the superantigens recited in claim 36. In addition, Kim et al. teach that TSST-1 and SEB bind MHC class II in a different fashion (see page 1873, third column, first complete paragraph). Regarding Jardetzky et al., said publication actually discloses that SEB c-terminal residues (eg. 210-217) are involved in MHC class II binding (see page 714, second column). Dohlsten et al. teach that "it would be of importance to further perturb MHC class II-dependent CTL activity by reducing the binding of the C215-SEA conjugate for MHC class II molecules" (see page 9291, column 1). Dohlsten et al. teach that MHC class II binding in SEA and other superantigens **has been localized to the C-terminal region** (see page 9291, first column). Dohlsten et al. teach that using such information, SEA/antibody conjugates with reduced MHC class II binding could be prepared (see column 1, page 9291). A routineer would have prepared such conjugates using routine experimentation. Dohlsten et al. teach that it would have been desirable to produce such mutated conjugates to decrease binding of the conjugate to nontumor cells which express MHC class II (see column 1, page 9291).

8. No claim is allowed.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644